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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,326	04/03/2006	Yusuke Nakamura	082368-003000US	9667

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EXAMINER	
GUSSOW, ANNE	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/526,326	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-76 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence Alignment*.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a polypeptide comprising the amino acid sequence of SEQ ID No. 2, 4, 6, 8, 10, and 12 in which one or more amino acids are substituted, deleted, inserted, and/or added. In view of this Peyman, et al. reads on the claim. Peyman, et al. teach SEQ ID No.2, a PNF1 protein, which is 96.8% identical to SEQ ID No. 4 of the present application. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked at to form a single general concept under rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, drawn to an isolated polypeptide.

Group II, claim(s) 2-4, 7 and 36, drawn to a polynucleotide, vector and host cell.

Group III, claim(s) 5, drawn to a method of producing a polypeptide.

Group IV, claim(s) 6 and 37, drawn to an antibody.

Group V, claim(s) 8-13, drawn to an antisense polynucleotide.

Group VI, claim(s) 14-16, drawn to an siRNA.

Group VII, claim(s) 20 in part, 17-19, and 21-25, drawn to a method of diagnosing colon cancer by detecting mRNA. If elected, these claims will be examined only to the extent that they relate to the use of mRNA.

Group VIII, claim(s) 20 in part, 17-19, and 21-25, drawn to a method of diagnosing colon cancer by detecting protein. If elected, these claims will be examined only to the extent that they relate to the use of a protein.

Group IX, claim(s) 26, drawn to a colon cancer reference expression profile.

Group X, claim(s) 27, drawn to a method of screening for a compound using a nucleic acid.

Group XI, claim(s) 28-29, drawn to a method of screening for a compound using cells and marker genes.

Group XII, claim(s) 30, drawn to a method of screening for a compound using protein and biological activity.

Group XIII, claim(s) 31, drawn to a method of screening for a compound using a cell and vector.

Group XIV, claim(s) 32, drawn to a method of screening for a compound using the polypeptide ARHCL1.

Group XV, claim(s) 33, drawn to a method of screening for a compound using the polypeptide NFXL1.

Group XVI, claim(s) 34, drawn to a method of screening for a compound using the polypeptide C20orf20.

Group XVII, claim(s) 35, drawn to a method of screening for a compound using the polypeptide CCPUCC1.

Group XVIII, claim(s) 38, drawn to an array.

Group XIX, claim(s) 39-41, drawn to a method for treating colon cancer using siRNA.

Group XX, claim(s) 42, drawn to a method for treating colon cancer using an antibody.

Group XXI, claim(s) 43, drawn to a method for treating colon cancer using a polypeptide vaccine.

Group XXII, claim(s) 44-45, drawn to a method for inducing anti-tumor immunity.

Group XXIII, claim(s) 46, drawn to a method for treating colon cancer using a compound.

Group XXIV, claim(s) 47, drawn to a composition for treating colon cancer comprising siRNA.

Group XXV, claim(s) 48, drawn to a composition for treating colon cancer comprising an antibody.

Group XXVI, claim(s) 49, drawn to a composition for treating colon cancer comprising a polypeptide.

Group XXVII, claim(s) 50, drawn to a composition for treating colon cancer comprising a compound.

Group XXVIII, claim(s) 51-58, drawn to a method of diagnosing gastric cancer.

Group XXIX, claim(s) 59, drawn to a method of screening for a compound for treating gastric cancer wherein the compound comprises a polypeptide.

Group XXX, claim(s) 60-61, drawn to a method of screening for a compound for treating gastric cancer wherein the compound comprises a cell expressing CGX 8.

Group XXXI, claim(s) 62, drawn to a method of screening for a compound for treating gastric cancer wherein the compound comprises a biological activity.

Group XXXII, claim(s) 63, drawn to a method of screening for a compound for treating gastric cancer wherein the compound reduces expression of a reporter gene.

Group XXX, claim(s) 64, drawn to a kit comprising a detection reagent that binds nucleic acid.

Group XXXIV, claim(s) 65, drawn to a kit comprising a detection reagent that binds a polypeptide.

Group XXXV, claim(s) 66-67, drawn to a method for treating gastric cancer using siRNA.

Group XXXVI, claim(s) 68, drawn to a method of treating gastric cancer using an antibody.

Group XXXVII, claim(s) 69, drawn to a method of treating gastric cancer using a polypeptide vaccine.

Group XXXVIII, claim(s) 70-71, drawn to a method for inducing anti-tumor immunity comprising the use of CGX8.

Group XXXIX, claim(s) 72, drawn to a method for treating gastric cancer using a compound.

Group XL, claim(s) 73, drawn to a composition for treating gastric cancer using siRNA.

Group XLI, claim(s) 74, drawn to a composition for treating gastric cancer using an antibody.

Group XLII, claim(s) 75, drawn to a composition for treating gastric cancer using a polypeptide.

Group XLIII, claim(s) 76, drawn to a composition for treating gastric cancer using a compound.

2. The inventions listed as Groups I-XLIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of Peyman, et al. the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups I-II, IV-VI, IX, XVIII, XXIV-XXVII, XXXIII-XXXIV and XL-XLIII represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The polypeptides of Groups I, XXVI, and XLII, the polynucleotide, vector and host cell of Group II, the antisense polynucleotide of Group V, the antibodies of Groups IV, XXV, and XLI, the siRNAs of Groups VI, XXIV, and XL, the expression profile of Group IX, the array of Group XVIII,

the compounds of Groups XXVII and XLIII, the reagent binding nucleic acid of Group XXXIII and the reagent binding a polypeptide of Group XXXIV are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the polypeptide is made by translation of mRNA, the antibody is raised by immunization, the siRNAs are generated by RNA processing, the expression profile is a combination of mRNAs, the array is made of either nucleic acid or protein probes, the compounds could be chemicals, antibodies, proteins or nucleic acids, the reagent binding nucleic acid could be a protein, mRNA or siRNA and the reagent binding a polypeptide could be a nucleic acid or another polypeptide. Furthermore, the polynucleotide and antisense polynucleotide can be used for hybridization screening, the polypeptide can be used for methods of treatment, the antibody can be used to immunopurify the polypeptide, and the compounds can be used for diagnosis or treatment of disease. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-II, IV-VI, IX, XVIII, XXIV-XXVII, XXXIII-XXXIV and XL-XLIII are patentably distinct.

The methods of Inventions III, VII-VIII, X-XVII, XIX-XXIII, XXVIII-XXXII and XXXV-XXXIX differ in the method objectives, method steps and parameters and in the reagents used. Invention III recites producing a polypeptide; Invention VII recites diagnosing colon cancer by detecting mRNA; Invention VIII recites diagnosis of colon cancer by detecting a protein; Invention X recites a method of screening for a compound using nucleic acid; Invention XI recites a method of screening for a

compound using cells and marker genes; Invention XII recites a method of screening for a compound using a protein; Invention XIII recites a method for screening for a compound using a cell and vector; Invention XIV recites a method of screening for a compound using ARCHCL1; Invention XV recites a method of screening for a compound using NFXL1; Invention XVI recites a method of screening for a compound using C20orf20; Invention XVII recites a method of screening for a compound using CCPUCC1; Invention XIX recites treating colon cancer using siRNA; Invention XX recites treating colon cancer using an antibody; Invention XXI recites treating colon cancer using a polypeptide vaccine; Invention XXII recites inducing anti-tumor immunity; Invention XXIII recites treating colon cancer using a compound; Invention XXVIII recites diagnosing gastric cancer; Invention XXIX recites screening for a polypeptide; Invention XXX recites screening for a cell expressing GCX8; Invention XXXI recites screening for a compound with biological activity; Invention XXXII recites screening for a compound that reduces expression of a reporter gene; Invention XXXV recites treating gastric cancer with an siRNA; Invention XXXVI recites treating gastric cancer with an antibody; Invention XXXVII recites treating gastric cancer with a polypeptide vaccine; Invention XXXVIII recites inducing anti-tumor activity using CGX8; and Invention XXXIX recites treating gastric cancer using a compound. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions III, VII-VIII, X-XVII, XIX-XXIII, XXVIII-XXXII and XXXV-XXXIX are separate and distinct in having different method steps and different endpoints and are patentably distinct.

3. Inventions IV, XXV, and XLI and XX, and XXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibodies of Groups IV, XXV, and XLI could be used for diagnosing or treating cancer, or for detecting a protein, for example.

Inventions VI, XXIV, and XL and XIX and XXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the siRNA molecules of Groups VI, XXIV, and XL could be used in a method of treatment, or for hybridization, for example.

Inventions XXVII and XLIII and XXIII and XXXIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the compounds of XXVII and XLIII could be used for diagnosing or treating disease, or in chemical reactions, for example.

Inventions I, XXVI, and XLII and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide could be made by a host cell, or vector in vitro, for example.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. If applicant elects any of Groups II, IV, VII-XIII or XVIII-XXVII, applicant must identify which one of the components, GCX1-7, are to be examined and the corresponding SEQ ID No.

If applicant elects any of Groups XIV-XVII, applicant must identify which one of the polypeptides, ARHCL1, NFXL1, MGC10334, CENPC1, C20orf20, BRD8, CCPUCC1, or nCLU, are to be examined.

If applicant elects any of Groups I, V, or XIX, applicant must identify the one SEQ ID No. that is to be examined.

This is not a species election.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

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